

Deriving Value from Integrated Operations and Business Planning within R&D

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Today's Speaker



Michael J. Ferrante – Florham Park, NJ

- Michael is an industry leader with twelve years experience in consulting, pharmaceutical planning and engineering. His area of expertise has been assisting firms to achieve transformational change through operations improvement.
- In this role, he helps pharmaceutical and biotechnology firms extract maximum value from their R&D portfolio through integrated operations and business planning.
- Prior to joining PwC, Michael was the Associate Director for R&D Capacity Planning & Management at Merck Research Labs. He also held positions in sales and operations planning, new products planning, supply chain management, and business process improvement.

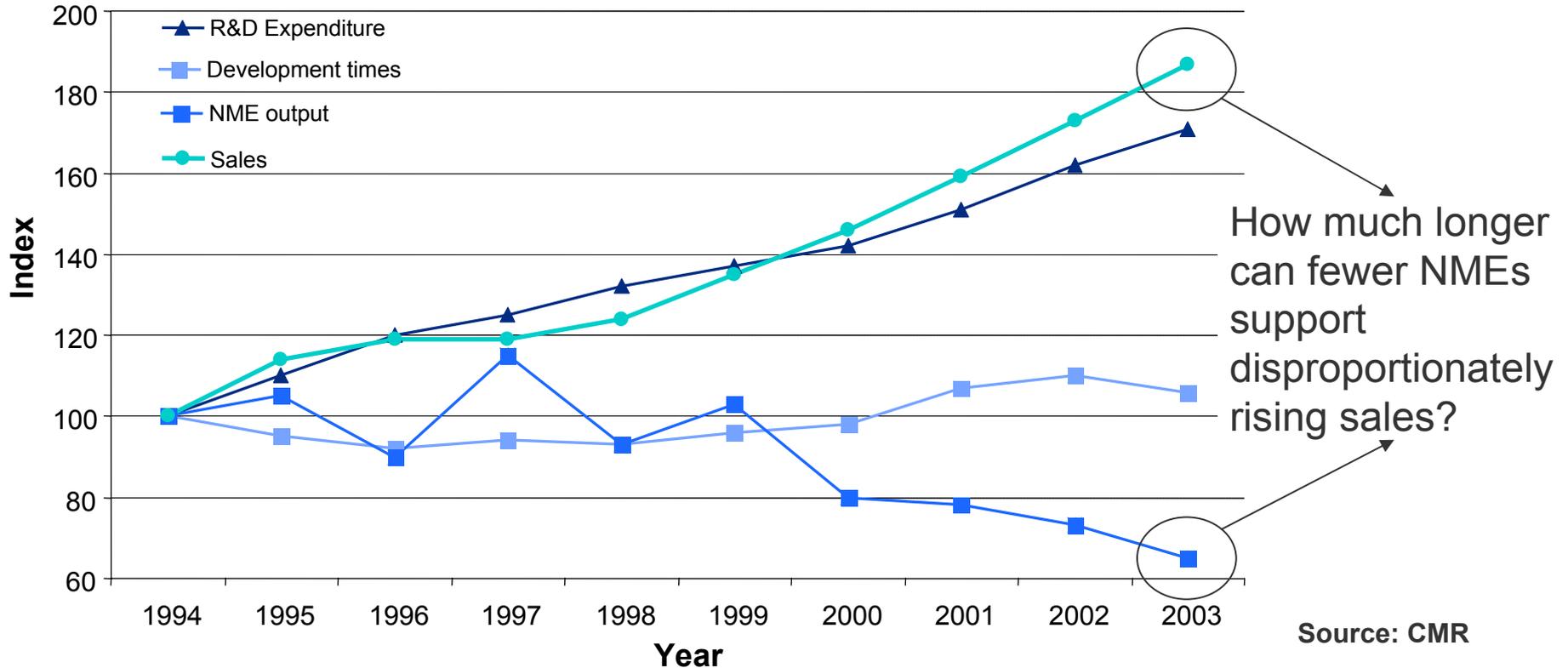
The “perfect storm” for pharmaceutical/biotech firms

- ▶ Realization that “blockbuster” model cannot be only development model to ensure continued success
- ▶ Cost of research and development has increased dramatically
- ▶ Probability of success (POS) of compounds in development has decreased due to the pursuit of more difficult and complex targets and indications
- ▶ Increased pressure from the financial markets to demonstrate continued innovation, revenue growth, and shareholder value
- ▶ Increased pressure from political figures and patient lobbying groups to reduce pharmaceutical prices while outputting novel medicines through R&D
- ▶ Increased regulatory pressure to ensure safety and efficacy through numerous complex and costly clinical studies involving thousands of patients

FDA has recognized the reduced output and increasing costs

The “current development path is becoming increasingly challenging, inefficient, and costly” as “the number of new drug and biologic applications submitted to FDA has declined significantly” while “the costs of product development have soared”.

US Food and Drug Administration (FDA)
“Innovation/Stagnation” Critical Path Initiative White Paper [2004]



Industry experts acknowledge that productivity and quality are core to fixing the “innovation problem”

“Many drug firms are focusing on ways to improve the efficiency and productivity of their R&D programs.... firms must improve management of their development portfolios.... improvements in R&D productivity will be tied to... enhanced risk management techniques..., better management of human resources, greater reliance on outsourcing and strategic relationships....”

“As companies seek ways to improve clinical decision-making efficiency.... the need to improve productivity and optimize resource allocation will impel greater use of risk assessment and management methodologies.... Firms will increase use of budgeting and portfolio optimization tools to reduce development times and out-of-pocket costs and improve attrition and clinical success rates.”

**Tufts Center for the Study of Drug Development
“Outlook 2004” Article [2004]**

More than innovative technologies are needed to deliver new treatments to patients. Productivity and quality improvements are also necessary to improve product pipelines. To do this, “drug developers must address big-picture issues such as creating more innovative R&D strategies....Firms will face growing pressure to improve R&D productivity to get new drugs to market sooner...and bolster return on investment”.

**Tufts Center for the Study of Drug Development
“Outlook 2005” Article [2005]**

How are firms reacting?

- ▶ Seeking economies of scale in research through consolidation
- ▶ Seeking value chain specialization (discovery, preclinical, early development, late development, marketing) rather than end-to-end expertise
- ▶ Raising the internal pressure to deliver more products through basic research and development with limited resources and budgets
- ▶ Firms are focusing on accountability to deliver projects on budget, while achieving product milestones
- ▶ Increasingly seeking collaborative agreements to stay competitive (joint-ventures, licensing, strategic relationships, partnerships, alliances, etc)
- ▶ Recognizing NIH is dead: increased willingness of bigger firms to license-in compounds and/or buy small firms, rather than relying solely on internal products

Which has raised the bar for operational efficiency

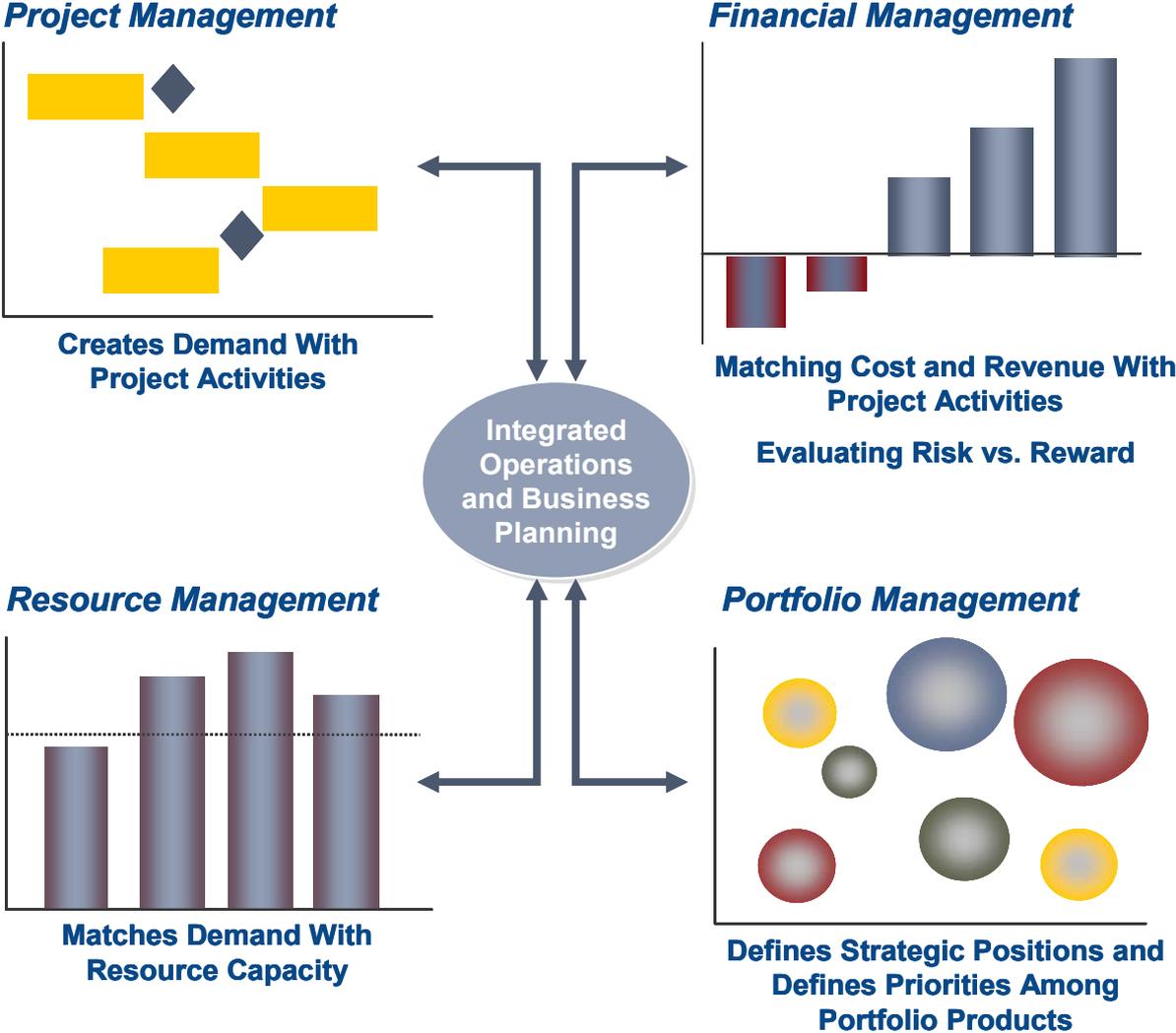
- ▶ Increased need to **contain costs** while implementing novel methods to increase the efficiency and productivity of the development chain
- ▶ Increased need for **scenario/decision analysis** and visualization tools to better understand organizational impact of options around key decision points to better optimize the development portfolio
- ▶ Increased need to **incorporate risk assessment** and risk management methodologies to portfolio and financial management to maximize value while mitigating the risks
- ▶ Increased need for tools to assist in **optimizing budget** and resource allocations
- ▶ Increased need to ensure that the organization as a whole is adhering to the same strategy and moving toward the **same goals and objectives**
- ▶ Increased need to **terminate compounds earlier** in the development cycle to reduce overall portfolio development costs
- ▶ Increased need to **outsource programs** or portions of programs to reduce overall development cost

But, organizations are realizing they cannot comprehensively answer key questions about their R&D operations

- ▶ Do we have the budget and internal resources to conduct the programs in our pipeline?
- ▶ How do we allocate / re-allocate budget and resources to meet our strategic objectives?
- ▶ If we modify one program, what effect does that have on other programs in the portfolio?
- ▶ If we modify budget/resources to a program, how will it affect the program timeline?
- ▶ How many people should we hire next year? What skills are needed and when do they need to be on board?
- ▶ How well are we executing on our development plans? What areas need improvement?
- ▶ Should we in-license or out-license a program? What are the associate costs and/or value?
- ▶ What programs will bring the most value to the organization? How do we value our products and technologies?
- ▶ Do we have defined and realistic project plans? How well are we executing on those plans?
- ▶ How accurate are our planning/forecasting assumptions? How well do they predict actuals?
- ▶ What metrics do we use to measure the throughput of our organization? Where do we stand relative to industry best practices?

Four key competencies embody Integrated Operations and Business Planning (IOBP)

The Operating Framework

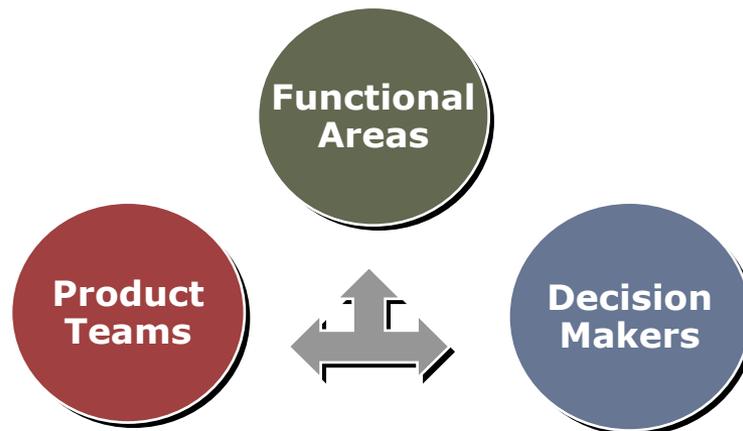


The How is as important as the What...

IOBP can help firms to derive the maximum value from their research and development chain by increasing throughput and operational effectiveness.

How is the value realized?

- ▶ Through identifying and fixing gaps in four key capabilities (Project Management, Financial Management, Resource Management, and Portfolio Management),
- ▶ By integrating these four competencies and aligning the strategic goals of organization with the day-to-day project and portfolio decisions
- ▶ By utilizing a process-based methodology to manage R&D operations by integrating the three major stakeholders:



IOBP Framework Principles

- ▶ **“One Set of Numbers”**
- ▶ **Activity-driven Resourcing and Budgeting**
- ▶ **Portfolio Visualization**
- ▶ **Data Transparency**
- ▶ **Development Chain Management**
- ▶ **Capacity Management**
- ▶ **Pipeline Throughput Metrics**
- ▶ **Integrated Data-Driven Analysis**
- ▶ **Sales and Operations Planning Models**
- ▶ **Standardized Project Plans and Multilevel Planning**

What drives organizations to recognize the need for IOBP?

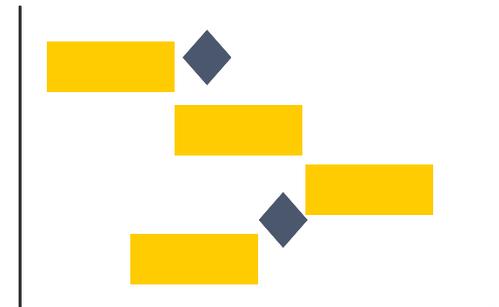
- ▶ A major pharmaceutical firm had low confidence that their proposed late-stage clinical trials could be **executed with budgeted costs and on-board resources** during their annual goal-setting session.
- ▶ A large pharmaceutical firm with a gap in the Phase II-III pipeline sought to quickly **bolster the portfolio with licensed-in compounds**. However, there was no reliable method to estimate development costs in order to inform the deal terms in a timely fashion.
- ▶ Pharmaceutical R&D senior management cannot quickly get an understand of where they are **placing their bets** and whether the resources and costs are deployed in alignment with the strategy
- ▶ A mid-sized biotech firm with a large portion of its activities outsourced needed to **get a handle on the external spend** required to support clinical studies.
- ▶ A global pharmaceutical firm with a complex regulatory activity set needed to understand its **“as-is” business process** and develop a **demand management process**.
- ▶ A high-growth biopharmaceutical firm realizes it needs an **enterprise project management** system, but has no experience in selecting, implementing, or realizing value for the firm through using such a tool.

IOBP Operating Framework - Project Management

Key Capabilities:

- ▶ Ability to ensure that the entire organization understands project priorities and executes on the defined and agreed upon project plan and associated timeline and budget
- ▶ Ability to standardize project plans, activities, and milestones to allow for enterprise-wide multi-level planning
- ▶ Ability to identify an evolving critical path and key decision points for clinical, safety, process and formulation pathways
- ▶ Ability to model intra-project scenarios and understand implication on cost and timing (i.e. in-sourcing, out-sourcing, additional indications, additional study arms, scope changes)
- ▶ Ability to set a project budget and baseline and understand sensitivity to timeline acceleration or deceleration
- ▶ Ability to reduce project timelines and bring critical decision point milestones forward, with limited resources and budgets
- ▶ Ability to create standardized project-centric planning reports to set project baseline and track progress against plan

Project Management



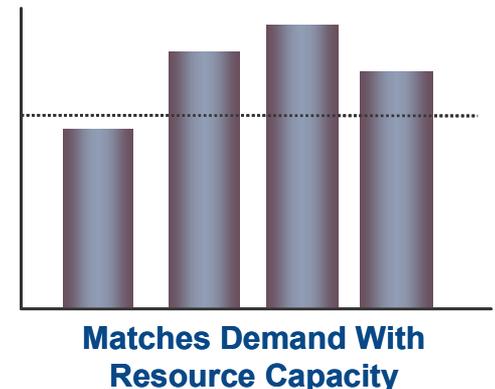
**Creates Demand With
Project Activities**

IOBP Operating Framework - Resource Management

Key Capabilities:

- ▶ Ability to translate prioritized activities into required development resources in a single, authoritative resource plan
- ▶ Ability to utilize parametric estimation to forecast future resource requirements over a defined planning horizon
- ▶ Ability to view available capacity by skill set and/or functional area
- ▶ Ability to summarize the resource requirements of all projects and compare against available capacity to ensure that sufficient resources are deployed onto all approved development programs
- ▶ Ability to translate resource requirements into hiring needs and facilities planning
- ▶ Ability to redeploy resources within a skill set or functional area in order to alleviate a resource bottleneck
- ▶ Ability to model cross-project scenarios and understand implication on resources (i.e. contract labor, cross-training, new facilities) and optimize resource deployment
- ▶ Ability to track actual effort against plan in order to improve resource requirements forecasting

Resource Management

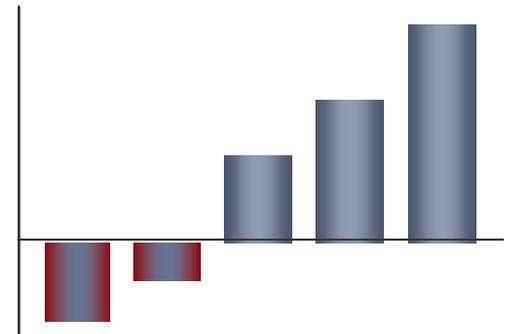


IOBP Operating Framework - Financial Management

Key Capabilities:

- ▶ Ability to appropriately define and allocate costs onto activities in the portfolio
- ▶ Ability to aggregate revenue and cost projections for all programs in development
- ▶ Ability to create an aggregated baseline budget/plan, capture actual costs and resources, and identify and track variances
- ▶ Ability to model project scenarios and understand implication on revenues and costs in order to maximize value (i.e. additional indications, shifting launch date, competitive forces)
- ▶ Ability to develop real-time NPV calculations based on marketing forecast inputs and real-time parametric forecasts of resources as portfolio parameters change

Financial Management



Matching Cost and Revenue With Project Activities

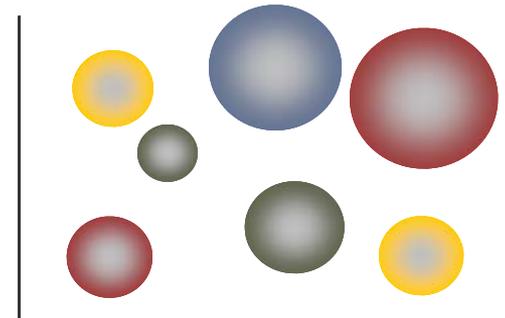
Evaluating Risk vs. Reward

IOBP Operating Framework - Portfolio Management

Key Capabilities:

- ▶ Ability to establish one authoritative, transparent source of planning data and assumptions with associated costs, benefits, risks, and priorities assigned
- ▶ Ability to do what-if analysis to determine the impact of one program change on the resources, timelines, and budgets of all other components of the portfolio
- ▶ Ability to visualize all portfolio elements along key dimensions to better inform strategic business decisions and provide senior management with the “big picture”
- ▶ Ability to analyze pipeline gaps and assess strategies to remedy (in-licensing, out-licensing, merger/acquisition, strategic partnerships and alliances)
- ▶ Ability to perform optimization on portfolio elements in order to maximize value, minimize risk, and increase throughput
- ▶ Ability to qualitatively and quantitatively determine relative risk and value attributes of each project in the portfolio in order to make key decisions (i.e. terminating unpromising compounds earlier, accelerating high-value, low-risk projects)
- ▶ Ability to generate and compile the data necessary to apply risk assessment and risk management methodologies across the portfolio to maximize value while mitigating risk

Portfolio Management



**Defines Strategic Positions and
Defines Priorities Among
Portfolio Products**

What is the impact if one part of the hub is missing or ineffective?

Planning Element	Impact if Element is Missing or Ineffective
Project Management	<p>Planning framework lacks the execution arm and becomes irrelevant.</p>
Financial Management	<p>No connection to the bottom line.</p> <p>Product/ resource decisions are not reflected in financial plan.</p>
Portfolio Management	<p>Planning becomes scheduling with no big picture or direction-setting.</p> <p>First-come, first-served for resources.</p> <p>Prioritization doesn't drive the business.</p> <p>No alignment between strategy and execution.</p>
Resource Management	<p>Business has no confidence in feasibility of plan.</p> <p>Constraints are hidden and bottlenecks are resolved inconsistently across products (portfolio gridlock).</p>

What are the consequences of insufficient operations planning?

- ▶ Without a single source of real-time planning data, firms may be making commitments to financial analysts or partner firms that are based on out-of-date or inaccurate data.
- ▶ When firms don't have real-time visibility on project costs, firms may underspend or overspend the total R&D budget and send inconsistent message to financial markets.
- ▶ Without visibility on the execution of key projects, projects on the critical path will be delayed, with an opportunity cost of up to \$1.3 MM per day.
- ▶ Without a process to execute on approved projects with confidence, credibility to deliver them erodes in the organization.
- ▶ When there is no way to translate strategy into operating decisions, there is no way to check long-term planning against reality.

Where is the pharma/device/biotech industry on this?

- ▶ Many firms have pockets of strong capabilities in one or more of the four key competencies
- ▶ Many firms have integration processes that are executed once a year
 - Long cycle times and data freshness
 - Unclear business linkage
 - Data dump vs. answering business questions
 - Data integrity
- ▶ Many firms are turning to industry-standard Enterprise Portfolio/Project Management tools (OPX2 is the industry standard) for integrating these capabilities
 - Tool must not define process; process must define tool
- ▶ Most firms are NOT extracting maximum value from integrated operations
 - Can be more a relatively more inexpensive investment
- ▶ We have a long way to go to achieve operational excellence found in other industries
 - Dynamic nature of our industry means that the solution will look different

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